Key Emergency Use Authorization and Medical Countermeasures Laws and Programs

Executive Overview

This document provides a brief overview of the key laws and programs related to FDA's Emergency Use Authorization (EUA) authority and other medical countermeasures initiatives. Additional details on these and other concepts are contained in other fact sheets in the ASTHO *Emergency Use Authorization Toolkit*.

Note: As of March 2012, Congress is in the process of reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA), which may impact a number of laws and programs described below. Please see *ASTHO EUA Current Issues Winter 2012* for more information about the PAHPA reauthorization and its potential impact on EUAs and related issues.

Laws

Emergency Use Authorization (EUA)

An Emergency Use Authorization (EUA) under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows for the special use of drugs and other medical products during certain types of emergencies. Specifically, an EUA permits the use of unapproved medical products (drugs, biologics [e.g., vaccines], and devices [e.g., diagnostics]) or the use of approved medical products in unapproved ways to diagnose, treat, or prevent serious diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) agents. FD&C Act §564 requires: (1) the determination by any of the U.S. secretaries of Health and Human Services (HHS), Homeland Security, or Defense that an emergency exists; (2) the declaration by the HHS secretary of an emergency justifying the authorization under FD&C Act §564; and (3) the issuance of an EUA by the Food and Drug Administration (FDA) commissioner upon a finding by the FDA that specified criteria have been met.

If all criteria are met, the FDA commissioner can issue a letter that authorizes the EUA. The letter must state: (1) the diseases or conditions the product may be used to diagnose, prevent, or treat within the scope of the EUA; (2) the known and potential benefits of the product; (3) conclusions concerning the safety and potential effectiveness of the product; (4) an assessment of the available scientific evidence; and (5) additional conditions of authorization, such as requiring that fact sheets to be distributed to healthcare professionals and the public with the EUA-authorized product.

An EUA does not contain or confer any tort liability protections by itself; however, medical products authorized under an EUA qualify as countermeasures (e.g., vaccines, drugs, devices) covered under the Public Readiness and Emergency Preparedness (PREP) Act if these medical products are identified as covered countermeasures in a PREP Act declaration. Medical products used pursuant to an EUA must also be used and administered according to the terms of the EUA for PREP Act coverage to arise.

Project BioShield Act

The Project BioShield Act of 2004 was enacted to accelerate the research, development, purchase, and availability of effective medical products against CBRN agents. Specifically, the Project BioShield Act authorizes expedited procurement, streamlined personnel appointments, expedited peer review, biomedical countermeasures procurement, emergency use of medical countermeasures, and other biodefense activities. The Project BioShield Act does not contain any explicit immunity or other liability protections, which proved to be an ongoing source of concern for potential developers of CBRN countermeasures. To address these and other concerns, the PREP Act was enacted to, among other things, provide liability protections to persons and entities involved in the development, sale, distribution, and administration of countermeasures.

Public Readiness and Emergency Preparedness Act (PREP Act)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the HHS secretary to issue a declaration that provides immunity from tort liability for claims of loss caused by countermeasures against diseases or other threats of public health emergencies. The act covers persons and entities involved in the manufacture, testing, distribution, administration, and use of covered countermeasures. A PREP Act declaration is different from and independent of other federal emergency declarations. A separate emergency declaration under Public Health Service Act Section 319 or another statute is not required for PREP Act immunities to take effect.

Programs

Federal Shelf Life Extension Program (SLEP)

The federal Shelf Life Extension Program (SLEP) extends the expiration dates on qualifying drugs and other materiel in federal stockpiles. SLEP is administered by the Department of Defense in cooperation with the FDA. SLEP is an acknowledgement that the actual shelf life of drugs and other medical products in the program may be longer than their stated expiration date. The purpose of SLEP is to defer replacement costs of stockpiled drugs by extending their useful life. SLEP is a fee-for-service program paid for by the federal agencies participating in the program; the Strategic National Stockpile participates in SLEP. Participating agencies are required to pay for the FDA's ongoing testing and analysis of the drugs and other medical materiel in the SLEP process. Products that pass testing are granted extended expiration dates but must undergo ongoing testing to monitor their continued shelf life. Products that fail testing at any time are destroyed. Products that do not receive additional extensions of their expiration dates or are not tested for SLEP are destroyed at their final expiration dates. SLEP is currently available only for federally-maintained stockpiles, although there have been ongoing deliberations between the federal government and the states about extending SLEP to state-maintained stockpiles or creating a separate SLEP-like program for state stockpiles.

Strategic National Stockpile (SNS)

The Public Health Service Act authorizes the HHS secretary in coordination with the secretary of Homeland Security, to maintain a stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile (SNS). State governors or their designees can request deployment of SNS assets when there has been an overt terrorist event that will harm the public's health or where epidemiological, laboratory, or other surveillance systems have identified unusual patterns of disease or deaths that may indicate a terrorist event or other national emergency. A federal or state emergency declaration is not required to request SNS deployment. States are not subject to cost-sharing requirements for SNS deployments, unlike other federal disaster assistance programs. Federal personnel work in conjunction with state and local officials to determine if and what components of the SNS are needed. Ultimately, the federal government is responsible for making the decision to deploy all or portions of the SNS. Each state has established plans for receiving and distributing SNS assets within the state.

The SNS is not considered a first-response tool, but rather a support mechanism for state and local response efforts. The SNS program is designed to supplement and resupply state and local inventories of medicines and supplies during emergencies. Several SNS stockpiles are strategically located in secured warehouses across the United States to ensure the timely deployment of materiel to any location in the country by land or air. Initial deployments from the SNS are 12-hour "Push Packages," which are caches of medicines and medical supplies that can address a range of needs arising from what may be an ill-defined threat in the early hours of an emergency event. If an event requires additional medicines and supplies, a deployment from managed inventory supplies is delivered within 24-36 hours. The SNS may also include medicines that have been authorized under the FDA's EUA authority. Medicines authorized by an EUA must be distributed and dispensed according to conditions outlined by the FDA in each EUA.

The Cities Readiness Initiative (CRI) focuses on emergency preparedness in the largest cities and metropolitan areas in the United States, where more than 50 percent of the nation's population resides. CRI has enabled public health departments in states and large metropolitan areas to develop plans to respond to large-scale bioterrorist events by dispensing antibiotics to the entire population of a specified metropolitan area within 48 hours.

This document was compiled from August 2011-March 2012 and reflects the laws and programs current at the time. It reflects only selected portions of the laws relevant to public health emergencies; it is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.